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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,092	02/06/2004	Ernesto A. Brovelli	AM1150	7125

24123 7590 06/19/2006

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,092	BROVELLI ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *8-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/6/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-7 in the reply filed on 5/2/06 is acknowledged. Claims 8-22 are hereby withdrawn from examination on the merits as they are directed toward a non-elected invention.

Claim Objections

Claim 5 is objected to because of the following informalities:

Claim 5 recites 'polysaccarides' which should be spelled 'polysaccharides'.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method using THP-1 cells, does not reasonably provide enablement for all cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, Applicant is claiming 'adding a preparation of the plant to a cell culture' and 'analyzing the cell culture for a level of a product that the medicinal plant induces'. These cells may be directed toward plant cells or other cells besides THP- 1 cells. The Instant specification does not teach what products would be induced in plant cells or cells besides THP-1 cells, nor does the prior art teach or suggest this information. Therefore, the skilled artisan could not use the invention for its intended scope.

To practice the invention would not only entail routine experimentation, but would involve rigorous testing in order to ascertain what products, if any are induced in cells besides THP-1 cells by interacting with Echinacea plant material. This testing would involve undue experimentation without any reasonable expectation, especially due to the enormous numbers of known plant, bacterial and mammalian cells known in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over A in view of C or B in view of C; wherein A = Seidler – Lozykowska et al. (2003), B= Dou et al. (2001 – Abstract) and C= Rininger et al. (2000).

Seidler – Lozykowska et al. (2003) analyzed the polyphenolic acid content of Echinacea purpurea during various growth stages of the plant (see Abstract and

Material and Methods). Seidler – Lozykowska et al. determined that "the highest concentration [of polyphenolic acids] was in the leave blades...during flowering stem formation in one year plants".

Dou et al. (2001- Abstract) taught assaying the level of cichoric acid in *Echinacea purpurea* plant material in different stages of growth (see Abstract). Dou et al. indicated that "The content of cichoric acid and yield were the highest in the overground part of *E. purpurea* before and after the bloomy stage" (Abstract).

Neither reference taught specifically wherein the plants at different stages were added to a cell culture to analyze products induced by Echinacea.

Echinacea was well known in the art for imparting immunological activity of macrophage cells according to Rininger et al. (2000). Specifically, Rininger et al. analyzed the production of TNF- α, IL-1α, IL-1βIL-6, IL-10 and nitric oxide from macrophage cells upon contact with several products of Echinacea including standardized extracts, whole plant material, juice and phenolic compounds (see entire reference, especially pages 4-10). Rininger et al. specifically stated that "Echinacea immunostimulatory activity varied significantly from lot-to-lot of raw material from the same supplier and may reflect growth conditions, time of harvest, milling and storage conditions" (p. 10).

One of ordinary skill in the art would have been motivated to harvest Echinacea at different growth stages to ascertain its immunopotentiality on macrophage cells in order to assess immuno-function of the plant at different stages. Analyzing Echinacea plants at different stages for particular immuno-potentiating compounds was known in the art according to Dou et al. as well as Seidler – Lozykowska et al. (2003), and Rininger et al. recognized that the variance of immunostimulatory activity was probably due to time of harvest *inter alia.* Thus, the ordinary artisan would have had a reasonable expectation that testing the Echinacea at varying growth stages for immunopotentiating activity would have determined an optimum harvest time for the Echinacea.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

The prior art of record and not relied upon is considered pertinent to Applicant's disclosure:

Barrett, B. MEDICINAL PROPERTIES OF ECHINACEA: A CRITICAL REVIEW; Phytomedicine, 10 (2003), pages 66-86.

Perry et al. ECHINACEA STANDARDISATION; ANALYITICAL METHODS FOR PHENOLIC COMPOUNDS AND TYPICAL LEVELS IN MEDICINAL SPECIES; J. Agric. Food Chem, 2001, 49, pages 1702-1706.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm. Friday

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

June 6, 2006